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09/759,747	01/12/2001	Norman E. Williams	1337	4893

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PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/06/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,747

Applicant(s)

WILLIAMS ET AL.

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 8 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 8 has been interpreted as if the recitation "the inbred maize plant of claim 2" read --the plant of inbred line PH6ME--. Claim 27 has been interpreted as if "the inbred maize plant of claim 21" read --the maize plant having all the physiological and physiological characteristics of inbred line PH6ME--.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,118,056 ('056). Although the conflicting claims are not identical, they are not patentably distinct from each other because

Art Unit: 1638

they both appear to be drawn to the same maize seeds, plants, plant parts and methods. The instantly claimed plants and the patented plants have different designations. The designation "PH6ME" of the instantly claimed cultivar is arbitrarily assigned, and does not provide any patentable distinction from the cultivar claimed in '056, PH1EM. Any differences between PH6ME and PH1EM are due to minor morphological variations that do not confer patentable distinction. The instantly claimed plants that are derived from crosses and breeding programs involving PH6ME or plants having the same morphological and physiological characteristics of PH6ME, and plants produced by genetic transformation of PH6ME, are not patentably distinct from the patented plants that are derived from crosses and breeding programs involving PH1EM or plants having the same morphological and physiological characteristics of PH1EM, and plants produced by genetic transformation of PH1EM. The instantly claimed methods are also not patentably distinct from the patented methods, as the plants used in the methods are not patentably distinct, and involve the same steps. The claims of '056 include a method of producing a maize plant comprising crossing a maize plant, having all the morphological and physiological characteristics of PH1EM wherein the plant has been transformed with a transgene, with a non-transformed plant of line PH1EM. Note that the plants produced by crossing a transformed PH1EM plant with a non-transformed PH1EM plant produced a PH1EM plant with a single gene conversion. It was obvious that the transferred gene could have been any dominant or recessive allele of any gene. A patent issuing from the instant application would then effectively extend the term of the claims of '056.

Art Unit: 1638

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "PH6ME" in claims 1, 6, 12, 14, 21, 25, 31, 33, 37, 40-42, and 44-46 render the claims and those dependent thereon indefinite. Since the name "PH6ME" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "PH6ME" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Amending claims 1, 6, 21, 25, 37, and 40 to recite the ATCC deposit number in which seed of corn inbred line PH6ME has been deposited would overcome the rejection.

In claims 14, 33, 41, 45, and 46: the terms "excellent" and "above average" are relative terms that have no definite meaning. The terms do not reasonably apprise one of the scope of the invention. The recitation "Central Corn Belt, Northwest, Northcentral, Northeast, Western, and Drylands regions of the United States" also renders the claims indefinite. It is not exactly clear what states or geographic areas make up these regions.

Art Unit: 1638

In claims 16 and 35: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the corn plant breeding program of claims 15 and 35, respectively. However, claims 15 and 35 are directed to methods, not programs. It is suggested that the recitation "corn plant breeding program" in line 1 of claims 16 and 35 be replaced with --method--.

In claims 19, 20, 48, and 49: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the single gene conversion(s) of claims 18 or 47. However, claims 18 and 47 are directed to maize plants.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3, 9-14, 17-20, 22, 28-33, 36-39, 41-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH6ME, or a corn plant having all the morphological and physiological characteristics of corn plant PH6ME wherein said plants are male sterile; any F₁ hybrid corn seed produced by crossing corn plant PH6ME with any other inbred corn plant; any F₁ hybrid corn

Art Unit: 1638

plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH6ME and expresses a combination of at least two PH6ME traits; any PH6ME-derived corn plant produced by crossing PH6ME with any other corn plant from 0-5 times; or the corn plant grown from PH6ME seed, wherein the plant has been transformed so that its genetic material contains or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH6ME plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH6ME is a source of breeding material; any PH6ME plant that further comprises any single gene conversion(s); a process for producing inbred line PH6ME comprising planting a collection of PH6ME hybrid seed and PH6ME itself; a method of producing PH6ME-derived plant comprising crossing PH6ME with another maize plant.

The specification describes morphological and physiological traits of an inbred corn plant arbitrarily designated "PH6ME" (page 17, lines 3-24, Table 1 on pages 18-20; page 35, line 28 to page 36, line 27; Tables 2A-2E and Table 3 on pages 38-43). The specification also indicates that hybrid plants were produced by crossing PH6ME to a corn plant designated PH4GP. Numerous traits of the PH6ME/PH21T hybrid were compared to other hybrid plants produced by crossing other inbred corn plants (page 36, line 30 to page 37, line 25; Tables 4A-4E, pages 44-52). The specification further indicates that upon allowance of any claims, all restrictions on the availability to a deposit of 2500 seeds of PH6ME with the American Type Culture Collection will be irrevocably removed and all requirements of 37 CFR 1.801-1.809 will be met (page 53).

However, the specification does not describe PH6ME as being male sterile. The specification discusses how plants may be manipulated to be male sterile (page 2, line 21 to page

Art Unit: 1638

3, line 14). However, the morphological and physiological description of plant PH6ME described in the specification does not indicate that it is male sterile.

The specification also does not describe the plants produced by the corn breeding programs, transgenic PH6ME plants, PH6ME plants comprising single gene conversion(s), or by crosses wherein at least one ancestor is corn variety PH6ME, other than PH6ME/PH21T. The morphological and physiological traits of the corn plants that are crossed with PH6ME, and with progeny of that cross, are unknown, and the description of progeny and descendants of corn plant PH6ME are unknown. The description of corn plant PH6ME is not indicative of the description of plants and seed produced by the breeding programs and crosses, or of any of its descendants. The claimed invention also encompasses plants that express at least two of the "PH6ME traits" listed in claims 14, 33, 41, 45, and 46. However, to say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by PH6ME. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant PH6ME. For example, Noble, Jr. (U. S. Patent No. 6,118,056) describes a corn plant, designated "PH1EM," which has at least two traits in common with PH6ME, a relative maturity of 109 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, and above average resistance to Gray Leaf Spot, for example (col. 10, lines 52-62). The instantly claimed corn plants could have PH1EM as an ancestor, as well as PH6ME, in which the relative maturity and Gray Leaf Spot resistance traits, for example, could have been inherited from PH1EM. The claims also encompass plants that do not have to express any of the traits that are expressed by PH6ME. The specification does not

Art Unit: 1638

describe any of the traits of such plants, and the morphological and physiological description of PH6ME is not indicative of the description of such plants. The description of the PH6ME/PH21T hybrid also does not provide any information concerning the description of any other hybrids. The morphological and physiological traits of PH6ME/PH21T are not indicative of the traits expressed by other hybrids. The descriptions of PH6ME and PH6ME/PH21T are also not indicative of any transgenic plant or PH6ME plants comprising single gene conversion(s). Further, the single genes that govern the traits contemplated in the specification at page 21, lines 20-23 are not described. Transgenes may also be of any gene, including those that effect more than one trait. The morphological and physiological characteristics of any such plant are not described. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from ^{PH6ME}, which are not described. Given the breadth of the claims encompassing corn plant PH6ME having male sterility, corn plants expressing at least two traits that are also expressed by PH6ME, or any trait, and descendents of PH6ME, and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

5. Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH6ME, or a corn plant having all the morphological and physiological characteristics of corn plant PH6ME; or wherein said plants are male sterile; tissue culture of regenerable cells from said plants; a maize plant regenerated from said tissue culture capable of expression all the morphological and physiological characteristics of PH6ME; method for producing a F₁ hybrid maize seed comprising crossing PH6ME with a different inbred maize plant; any F₁ hybrid corn seed produced by crossing corn plant PH6ME with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH6ME and expresses a combination of at least two PH6ME traits; any PH6ME-derived corn plant produced by crossing PH6ME with any other corn plant from 0-5 times; or the corn plant grown from PH6ME seed, wherein the plant has been transformed so that its genetic material contains or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH6ME plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH6ME is a source of breeding material; any PH6ME plant that further comprises any single gene conversion(s); a process for producing inbred line PH6ME comprising planting a collection of PH6ME hybrid seed and PH6ME itself; a method of producing PH6ME-derived plant comprising crossing PH6ME with another maize plant, or wherein said method further comprises plant tissue culture methods.

Since the claimed seed of maize inbred line PH6ME is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily

Art Unit: 1638

available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public.

If the seeds are deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-49 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Noble, Jr. (U.S. Patent No. 6, 118,056).

The claims are broadly drawn towards a corn plant produced by growing seed of any corn inbred line designated PH6ME, or a corn plant having all the morphological and physiological characteristics of corn plant PH6ME; or wherein said plants are male sterile; tissue culture of regenerable cells from said plants; a maize plant regenerated from said tissue culture capable of expression all the morphological and physiological characteristics of PH6ME; method for producing a F₁ hybrid maize seed comprising crossing PH6ME with a different inbred maize

Art Unit: 1638

plant; any F₁ hybrid corn seed produced by crossing corn plant PH6ME with any other inbred corn plant; any F₁ hybrid corn plant produced by growing said hybrid corn seed; any maize plant wherein at least one ancestor is PH6ME and expresses a combination of at least two PH6ME traits; any PH6ME-derived corn plant produced by crossing PH6ME with any other corn plant from 0-5 times; or the corn plant grown from PH6ME seed, wherein the plant has been transformed so that its genetic material contains or more transgenes operably linked to regulatory elements, and progeny thereof; a method for producing a maize plant comprising crossing said PH6ME plant that comprises one or more transgenes; any corn plant or parts thereof, produced in a method for developing a corn plant in a plant breeding program wherein PH6ME is a source of breeding material; any PH6ME plant that further comprises any single gene conversion(s); a process for producing inbred line PH6ME comprising planting a collection of PH6ME hybrid seed and PH6ME itself; a method of producing PH6ME-derived plant comprising crossing PH6ME with another maize plant, or wherein said method further comprises plant tissue culture methods.

Noble, Jr. teaches seed of an inbred maize line designated "PH1EM," plants produced by growing said seed, and plants and plant parts having all of the physiological and morphological characteristics of PH1EM (col. 10, line 52 to col. 12, line 7, Table 1; claims). It appears that the claimed plants and seeds of the instant invention may be the same as PH1EM, given that they exhibit the same traits, a relative maturity of 109 based on the Comparative Relative Maturity Rating system for harvest moisture of grain, and above average resistance to Gray Leaf Spot, for example (col. 10, lines 52-62). Alternatively, if the claimed plants, plant parts, and seeds of PH6ME are not identical to PH1EM, then it appears that PH1EM only differs from the instantly

Art Unit: 1638

claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH6ME. Noble, Jr. also teach methods to confer male sterility and plant PH1EM where it is further male sterile; production of tissue culture of regenerable cells from a plant of line PH1EM, wherein regenerable cells are from tissues including flowers, pollen, ovules, among others; a plant produced from tissue culture of PH1EM that is capable of expressing all of the morphological and physiological traits of PH1EM; methods for producing hybrid seeds and plants wherein a plant of inbred line PH1EM is crossed with another inbred corn plant, and the ensuing seed are harvested, or wherein the method further comprises utilizing plant tissue culture methods to derive progeny; corn plant breeding programs, including backcrossing, pedigree breeding, recurrent selection, among others; method for producing PH1EM inbreds comprising planting a collection of seed of PH1EM and a hybrid, one of whose parents is PH1EM, and identifying inbred PH1EM by decreased vigor or identifying seed or the inbred plants with homozygous genotype; PH1EM comprising transgenes operably linked to regulatory elements, introduced via genetic engineering or breeding, as well as crossing the transformed plant with another plant to produce progeny comprising the inherited transgene; and crossing two corn plants wherein either one or both parents is PH1EM, and crossing the resultant plant with itself or another corn plant to derive further progeny, and repeating such crossing 0 to 5 times; and an F₁ hybrid produced by crossing PH1EM with inbred PH2KN (col. 2, line 4 to col. 5, line 20; col. 15, line 29 to col. 25, line 32; col. 27, line 10 to col. 28, line 26; claims). Note that the plants produced by crossing a transformed PH1EM plant with a non-transformed PH1EM plant

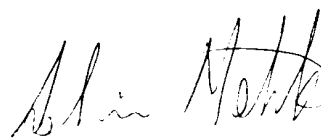
Art Unit: 1638

produced a PH1EM plant with a single gene conversion. It was obvious that the transferred gene could have been any dominant or recessive allele of any gene. The claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Noble, Jr.

7. No claim is allowed.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

July 25, 2002